

REMARKS

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request entry of the amendment and reconsideration of the claims in view of the remarks presented below.

Applicant disagrees with the Examiner's position that the current claims do not find support in 09/563946 (the '946 application) or provisional application 60/185561 (the '561 application). Applicant respectfully submits that the claims are based upon the disclosure of both the provisional application and the '946 application. Applicant believes that one skilled in the art would be able to discern from the disclosure of either the '561 or 946 applications that the Applicants had possession at the time the application was filed of the subject matter claimed in claim 30 and its dependent claims.

"Heat is generated by metabolic activity in the body." '561 at page 1, ll. 13-14 Ordinary body activities generate heat. *Id.* at 2, l. 1. The temperature of the body can be controlled by adding or removing heat from the body. *See, e.g.*, the disclosure at pages 1, ll. 10- page 3, ll. 31. Cooling blankets are too slow or inefficient to cool a patient; that is, they cannot remove heat from a body at a fast enough rate. *Id.* at pg 2, ll. 22-28.

The heat transfer liquid of an intravascular heat exchanger exchanges heat with the blood at a heat transfer region to change the temperature of the blood, and thus a patient. *Id.* at pg 3, ll. 19-28. The fluid is then circulated to an external heat exchanger to add or remove heat lost or gained from the interaction of the intravascular heat exchanger and the blood of the patient. *Id.* at ll. 28-29. "In this manner the temperature of the blood and ultimately of the patient may be controlled by controlling the temperature of the external heat exchanger." *Id.* at ll. 30-31.

To summarize, at this point, one skilled in the art knows from the specification that a body generates heat as a function of body activity. Knowing this, he knows that the heat generation varies as a function of activity. The artisan also knows that to change the temperature of a body, a device, such as an intravascular heat exchanger, must add or remove heat from (or to) the blood at a rate faster than the body is generating or losing heat. (Note, for simplicity, the argument will focus on heat removal from the body; the artisan would immediately understand that the same arguments apply to heat addition).

The artisan also knows that this is accomplished by "controlling the temperature of the external heat exchanger." One skilled in the art would immediately understand that controlling the temperature of the external heat exchanger implies that the temperature of the heat exchanger is not fixed, but is variable.

Returning to the specification, "intravascular heat exchangers exchange a significant amount of energy, for example more than 100 watts. This is achieved by maintaining a maximum ΔT between the heat exchange fluid and the blood, and flowing a maximum amount of heat exchange fluid through the circuit. A heat exchange fluid that can be maintained between 0°C and 42°C is generally preferable." '561 at pg 4, ll. 1-4.

One skilled in the art knows that a watt is a measure of the rate of change of energy over time, that is, 1 watt=1 joule/sec. *See*, Webster's New World College Dictionary, 4th ed., page 1618, a copy of which is attached hereto as Appendix 1. Moreover, the artisan knows that such heat exchange is maximized by maximizing the ΔT between the fluid and the blood, as well as the rate of fluid flow through the intravascular heat exchanger. Knowing that up to more than 100 watts of energy can be exchanged by maximizing ΔT and fluid flow, the artisan knows that Applicants have inherently disclosed that the intravascular heat exchanger can exchange less than 100 watts, depending on the ΔT and fluid flow, parameters that are controlled by the controller of Applicant's claimed invention. *See*, '561 at pg 3, ll. 30-31.

One embodiment disclosed in the '561 application discloses use of a TE cooler for altering the temperature of the heat exchange fluid, stating: "A TE cooler is particularly advantageous because the same unit is capable of either generating heat or removing heat by changing the polarity of current activating the unit." '561 at pg. 9, ll. 21-25. *See also*, pg 9, ll. 30 - pg 10, ll. 3. One skilled in the art would understand that TE devices are not "instant on/off" devices. That is, when a TE device is actuated to cool, the cooling power of the device increases for a period of time until the TE device reaches equilibrium. Thus, the rate of cooling of the heat exchange fluid being cooled by the TE device varies until the ΔT between the fluid and TE cooler is at a maximum. The same effect is seen at the in intravascular heat exchanger as the ΔT of the fluid in intravascular heat exchanger reaches a maximum compared to the temperature of the blood.

Moreover, the specification discloses that the TE device changes from heating or cooling by changing the polarity of the current activating the TE unit. An artisan would know that because it is the current that controls the operation of the device, the current may also be controlled to increase or decrease the heating or cooling power of the TE unit. Increasing or decreasing the heating or cooling power of the TE unit affects the temperature of the heat exchange fluid, which affects the ΔT between the intravascular heat exchanger and the blood of the patient, which, as stated previously, the artisan knows will affect the rate of energy removal (or addition to) from the blood. In this manner, one skilled in the art would know that Applicants possessed the concept of controlling the rate of energy exchange between the blood and the intravascular heat exchanger at the time the provisional application was filed.

Claim 30 recites actuating the controller increase or decrease a rate of heat addition or removal as a function of the temperature differential between the target temperature and the body temperature. As discussed above, the specification of the '561 application clearly supports this claim. While there is wording in the specification that states "For example, it may actuate the TE cooler 11 to increase the amount of heat it is removing . . . ", the specification more broadly discloses, at least inherently, that Applicants also had in their possession at the time of filing the concept of controlling the rate of heat removal. Applicants respectfully submit that one skilled in the art would immediately know that, from the rest of Applicants' disclosure, "the amount of heat" implicitly refers to a change in the rate of heat addition or removal. Moreover, from the subject matter of the disclosure, the artisan would know that if a controller can control the temperature of the heat exchange fluid over time, the controller may also control any rate of change of that ΔT , thus also controlling a ramp rate of the ΔT .

For all these reasons, Applicants believe that claim 30, and its dependent claims, are fully supported by the specification of the '561 and '946 applications, and that Applicants' claim of priority to those applications is proper.

Claims 30-34 and 36-37 were rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg WO 00/10494. Claim 35 was also rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg. Applicants respectfully traverse these rejections on the basis that

the priority date of the claims is February 28, 2000, which is before the publication date of Ginsburg. Accordingly, Ginsburg is not prior art to the claims.

For all the reasons set forth above, Applicants respectfully submit that the rejections based on Ginsburg have been overcome for all claims, and request that the rejections be withdrawn and the claims allowed.

CONCLUSION

Applicant has carefully reviewed the arguments presented in the Office Action and respectfully requests reconsideration of the claims in view of the remarks presented. In light of the above amendments and remarks, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Should the Examiner have any questions concerning the above amendments and arguments, or any suggestions for further amending the claims to obtain allowance, Applicant requests that the Examiner contact Applicants attorney, John Fitzgerald, at 310-242-2667.

Please charge any additional fees payable in connection with this Amendment to our Deposit Account No. 06-2425.

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Respectfully submitted,

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